

# MedinCell publishes its first-half 2020/2021 financial results (April - September 2020): operating expenses and portfolio development in line with expectations

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# Main developments concerning the product portfolio during the first half:

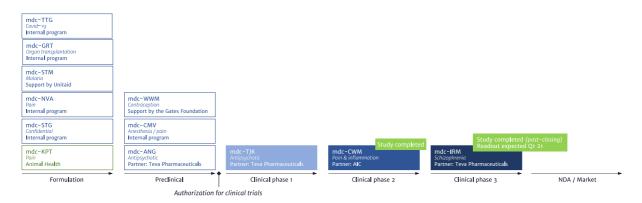
- · mdc-IRM program (schizophrenia)
  - Phase 3 Pivotal efficacy study: recruitment completed in May and study completed in November (post-closing)
  - Study Readout anticipated in the first quarter of 2021
  - Validation of manufacturing and transport procedures for the polymers on an industrial scale

# • mdc-CWM program (post-operative pain):

- Phase 2 study completed in April
- Meeting between AIC, MedinCell and the FDA in August 2020 to discuss the results of Phase 2 and the next steps in clinical and regulatory development
- Large-scale clinical studies expected to start in the first half of 2021

#### Other programs

- Progress in the regulatory development of two other antipsychotics: mdc-TJK in Phase 1 and mdc-ANG in preclinical development
- mdc-TTG program (Covid-19): Launch in September of an initial clinical trial to validate the safety of continuous administration of Ivermectin in oral form and selection of a 1-month active injectable formulation to launch preclinical activities in December (post-closing)
- Final formulations selected or on the verge of being selected for several programs opening the way for preclinical development: mdc-GRT (organ transplantation), mdc-NVA (pain), and mdc-KPT (animal health-pain)



# Stronger consolidated financial position at September 30, 2020 compared to the beginning of the semester:

- 27.5 M€ in cash
- 3.8 M€ in risk-free financial assets (0.7 M€ current + 3.1 M€ non-current) including 1.5 M€ provided as collateral for a bank loan
- Post-closing: 1.8 M€ in additional non-dilutive financing (PGE) received from BPI (October) and receipt of 5 M€ representing the final tranche of the EIB loan (November)

#### Key events of the period

*April* 2020 – Announcement of the launch of a Covid-19 program (mdc-TTG) aimed to develop a long-acting injectable Ivermectin formulation to protect people who are not infected with Covid-19.

April 2020 – Selection of the candidate formulation for the mdc-WWM program, which can now enter preclinical development. MedinCell has demonstrated *in vivo* the feasibility of a contraceptive administered by subcutaneous injection, fully bioresorbable and active for six months. This program is being developed with the support of The Bill & Melinda Gates Foundation through a grant of up to \$19 million over four years to fund preclinical activities and initial clinical studies.

May – June 2020 – MedinCell, which took proactive actions to prepare itself for the possible consequences of the serious crisis linked to Covid-19, received 11.9 M€ in non-dilutive financing in the form of PGE (state-guaranteed) loans arranged with Banque Populaire du Sud, BNP Paribas and Caisse d'Épargne.

June 2020 - MedinCell completed a capital increase in the form of a private placement of new shares raising a final gross amount of 15.6 M€. The operation was a great success and benefited from major support among existing shareholders and French and international investors. The proceeds of the capital increase will further strengthen the Company's ability to fund its R&D activities, including the expansion and further development of its portfolio of longacting injectable treatments.

September 2020 — Launch of the first clinical trial in the mdc-TTG program that aims to protect against Covid-19. This clinical trial aims to validate the safety of continuous administration of Ivermectin in oral form. In parallel, several long-acting injectable formulations based on MedinCell's BEPO $^{\otimes}$  technology are being tested *in vivo*. A 1-month active injectable prophylactic treatment should be ready to commence development for regulatory purposes by the end of 2020.

November 2020 (post-closing) — Phase 3 pivotal efficacy study completed in the United States for the mdc-IRM program, an experimental long-acting subcutaneous injectable treatment of risperidone for schizophrenia. Teva Pharmaceuticals, which funds and oversees the development of the program, expects to have the trial readout during the first quarter of 2021.

October – November 2020 (post-closing) — Strengthening of the Company's financial resources with an additional 1.8 M€ non-dilutive financing (PGE) received from BPI (October) and receipt of 5 M€ representing the final tranche of the European Investment Bank loan. The terms under which this tranche of the EIB loan may be drawn down had been renegotiated in June 2020. The EIB had provided MedinCell in March 2018 with 20 M€ in support that could be cashed in three tranches. The first two were paid to MedinCell in June 2018 and July 2019. This loan is repayable after June 1, 2023.

Changes in the Executive Board — Franck Pouzache, who joined MedinCell in April as Chief Human Resources Officer, was appointed by the Supervisory Board to the Company's Executive Board in September. Franck Pouzache has over 25 years' experience as a human resources executive to his name and has worked in the technology, nuclear and medical industry in France and the United States. Nicolas Heuzé, Chief Corporate Development Officer, left the Company at the end of October to pursue new business ventures after devoting close to 7 years to MedinCell's operational and financial development.

#### Details of the product portfolio's development at the end of the first half

At September 30, 2020, the portfolio consisted of:

- > 3 products in regulatory clinical development, with the most advanced set to complete its Phase 3 trials in the United States
- > 3 drug candidates in regulatory preclinical development phases
- > 6 products at the formulation stage (this preliminary phase aims to deliver a product prototype meeting the target specifications, including the duration of action and the dose of active ingredient to be regularly released)

Of these products in regulatory development or at the formulation stage:

- > 6 are being developed with industry partners such as Teva Pharmaceuticals, which is leading and funding the clinical development of 3 antipsychotics using BEPO® technology, or with the financial support of foundations and health agencies, such as the Bill & Melinda Gates Foundation and Unitaid.
- > 6 are directly funded by MedinCell.

11 products at the formulation or the regulatory development stage are for human health, and 1 product at the formulation stage is for animal health applications.

#### PROGRAMS AT CLINICAL STAGE

# **Subcutaneous injection**

mdc-IRM Treatment of schizophrenia Partner: Teva Pharmaceuticals	The Phase 3 pivotal efficacy study has been completed (post-closing). Analysis of the results is expected in the first quarter of 2021.	
mdc-TJK Antipsychotic Partner: Teva Pharmaceuticals	The first-in-human study for the investigational long-acting injectable antipsychotic mdc-TJK has started in Q4 2019. The results of this study, expected during 2021, will inform future development.	
Intraarticular injection		
mdc-CWM Post-operative pain and inflammation Partner: AIC	AIC and MedinCell met with the FDA in August 2020 to discuss the results of Phase 2 and the next steps in clinical and regulatory development. Final preparation is underway for large-scale clinical studies, which are scheduled for the first half of 2021.	

# NEXT POTENTIAL CANDIDATES FOR CLINICAL DEVELOPMENT

# **Subcutaneous injection**

mdc-ANG Antipsychotic Partner: Teva Pharmaceuticals	Status at September 30, 2020: preclinical Preclinical work continues to progress and will inform a decision on further development expected in the second half of 2020.
mdc-TTG Covid-19 MedinCell program	A clinical trial was launched in September 2020 to demonstrate the safety of Ivermectin when taken regularly in oral form over 4 weeks to simulate the continuous release of the active ingredient by a long-acting injectable.  An initial formulation is due to be selected by the end of the year so clinical development can commence immediately.
mdc-GRT Organ transplant MedinCell program	A candidate formulation is about to be selected after <i>in vivo</i> studies ( <i>post-closing</i> ). The program is all set for regulatory preclinical development to begin in 2021.
mdc-WWM Contraception Partner: Bill & Melinda Gates Foundation	Status at September 30, 2020: preclinical The CMC activities are underway ahead of the GLP-tox studies in 2021. The clinical trials are scheduled to begin in 2022.
mdc-STM Malaria Partner: Unitaid	Status at September 30, 2020: formulation
mdc-STG Indication: confidential MedinCell program	Status at September 30, 2020: formulation
dc-KPT (animal health)  A candidate formulation has been selected based on in vivo studies, and regulatory development will start in 2021.  edinCell program	

N.B. Plans to set up a joint venture with Cornerstone Animal Health have been abandoned definitively. That has had no impact on the progress made by the animal health programs, which remain in MedinCell's ownership.

# **Perineural injection**

The two products below are the first in MedinCell's portfolio with perineural administration

<b>mdc-CMV</b> Pain	Status at September 30, 2020: preclinical	
MedinCell program	The results of the first preclinical studies do not make it possible to envisage going into the clinic now Further investigations are still in progress. Activities are on stand-by at the moment	
mdc-NVA Pain MedinCell program	Status at September 30, 2020 A candidate formulation is likely to be selected in early 2021 on the basis of the full results of ongoing studies.	

#### Covid-19 crisis and MedinCell's financial visibility

From the start of the the Covid-19 pandemic and related economic crisis, the health and well-being of its employees have been MedinCell's top priorities. As part of its preventative approach, in line with the health authorities' directives, MedinCell introduced a travel ban and a homeworking policy from March 2020. The Jacou facility, close to Montpelier, was set up under the business continuity plan to ensure that the laboratory operations could continue during the lockdown without any threat to the health and safety of employees.

Given the uncertainties as to the scale, length and effects of the crisis, MedinCell rapidly introduced measures to unlock savings during the first quarter. Strategic research and development programs were not affected, while other activities were postponed, leading to some of the teams working part-time between April and June 2020. MedinCell's objective was to maintain a high level of financial visibility.

Several financing operations have been completed during the period to increase its cash position and to keep its programs moving forward.

- > 11.9 M€ of non-dilutive financing in the form of a State-Guaranteed Loan May and June 2020
- > Renegotiation of the drawdown conditions for the final tranche of the EIB loan June 2020.
- > 15.6 M€ capital increase Private placement June 2020

At September 30, 2020, due to reactivity and adapted management, MedinCell held sufficient cash to achieve its strategic objectives and cover its working capital requirement through to the second half of 2022, excluding the mdc-TTG program.

#### Selected first-half 2020 financial information

#### Financial visibility strengthened

At September 30, 2020, MedinCell held 27.5  $M \in \text{in cash}$ , plus 3.8  $M \in \text{in risk-free}$  financial assets. Six months earlier at the beginning of the financial year, it held 12.4  $M \in \text{in cash}$  and 3.6  $M \in \text{in financial}$  assets. During the first six months of the financial year, 11.9  $M \in \text{in non-dilutive}$  financing in the form of PGE loans (state-guaranteed) were negotiated and received. In addition, a capital increase of a gross amount of 15.6  $M \in \text{and}$  subscribed for by French and international qualified investors was completed successfully through a private placement of new shares. In addition to its available cash, MedinCell can count on the final 5  $M \in \text{tranche}$  of the total 20  $M \in \text{loan}$  awarded by the European Investment Bank, the drawdown terms for which were renegotiated in June 2020. This final tranche was in the end drawn down by MedinCell in November 2020 (post-closing).

#### Cash flow statement

	(€ thousands)	09/30/2020 6 months	09/30/2019 6 months
Α	Net cash generated/(used) by operating activities	(6,658)	(9,081)
В	Net cash generated/(used) by investing activities	(432)	(441)
С	Net cash generated/(used) by financing activities	22,165	4,361
	Change in net cash position	15,074	(5,161)
	Cash and cash equivalents at start of period	12,377	21,284
	Cash and cash equivalents at end of period	27,451	16,123

# A - Net cash generated/(used) by operating activities

During the first six months of the financial year, MedinCell's operations consumed 6.7 M€ in cash, in line with expectations, compared to 9.1 M€ in the previous period. Note that the 3.2 M€ CIR (Research Tax Credit) corresponding to 2019 was received during the period. In contrast, the 2.5 M€ credit for 2018 before was not received during first half of the previous year. MedinCell recorded a first-half net loss of 10.8 M€, compared to 9.0 M€ one year earlier. The difference was attributable to the revenue contraction (see section A below) and the reevaluation of the EIB debt cost, triggered by the June supplemental agreement concerning variable payments.

#### B – Net cash generated/(used) by investing activities

During the first six months, MedinCell continued to invest in protecting its intellectual property portfolio (97 K $\in$ ) and purchasing laboratory equipment (253 K $\in$ ).

#### C – Net cash generated/(used) by financing activities

During the first six months of the current financial year, MedinCell successfully completed several financing transactions to ensure it can fund its R&D activities while maintaining a high level of financial visibility. It received 11.9 M $\in$  in non-dilutive financing in the form of PGE loans (state-guaranteed) arranged with Banque Populaire du Sud, BNP Paribas and Caisse d'Épargne, and it raised a gross amount of 15.6 M $\in$  from a capital increase through a private placement. MedinCell also renegotiated the drawdown conditions for the final tranche of the EIB loan.

Post-closing: MedinCell in the end received the final tranche of the EIB loan in November 2020, plus another 1.8 M€ PGE loan from BPI in October 2020.

Given the available resources and the pace of cash consumption, MedinCell boasts solid financial visibility. Furthermore, it should continue to benefit from revenue from existing partnerships such as service revenue and milestone payments, as well as from the research tax credit.

#### Income statement

#### A - Revenue: 3.1 M€ (-20%)

First-half 2020 revenue derived solely from services for the formulation activities related to product formulation developed with industry partners: (i) partnership arrangements with the Bill & Melinda Gates Foundation to develop an injectable female contraceptive active for 6 months and a long-acting injectable prophylactic treatment for HIV (ii) collaboration with the Unitaid international agency in a project that aims to reduce malaria transmission. The revenue contraction compared to the same period of the previous period reflected the absence of any milestone payments from partners during the first six months.

MedinCell wishes to point out that the first revenue streams from product sales are expected to be royalties generated by the commercialization of products developed with its partners. In meantime, due to the product development cycle and depending on the financial terms of partnerships (which may or may not include certain elements such as services fees, milestone payments, royalties, cost sharing, profit sharing, etc.), its revenue may vary significantly from one period to the other.

# Other income from ordinary activities

MedinCell's Research and Development (R&D) activities qualify it to benefit of the Research Tax Credit. In line with the forecast, this amounted to 1.9 M€, an identical amount to the same period of the previous period, reflecting the importance of MedinCell's R&D activities.

# B – Recurring operating expenses: 11.3 M€ (-6%)

Operating expenses edged below their level in the same period of the previous year. In all, 69% of expenditures were devoted to R&D, and this line item remained stable throughout the period. In line with MedinCell's forecasts and strategy of expanding its product portfolio, R&D spending covered the cost of financing the CRO and CMO services to advance the current formulation research and preclinical study programs in order to pave the way for the next stages. At the beginning of the period, MedinCell introduced austerity measures, which included the deferral of certain expenditures and partial activity for certain teams. Sales and marketing expenses decreased by 39% compared to the same period of the previous year as certain vacant positions were not filled. In addition, the pandemic crisis prevented all travel and led to the curtailment of the strategic marketing, market access and business development teams' activities in the first six months of the financial year, causing their expenditure to be deferred.

General & administrative costs remained stable over the period, including staff expense. However, professional fees increased over the period, largely as a result of fees related to the capital increase, which was completed successfully in June 2020.

# C- Financial expenses: 2.6 M€

Net financial expense of 2.6 M $\in$  reflected interest on various borrowings, composed mainly by the bonds and the EIB loan, after taking into account the 6-month interest moratorium on certain loans. This amount also includes a revised estimate of 1.3 M $\in$  in respect of the past and future cash flows linked to the variable remuneration applicable on the EIB loan. The terms of the variable interest arrangements were amended in the June 2020 amendment laying down the payment terms for the third and final 5 M $\in$  EIB loan tranche.

# Consolidated income statement

	(€ thousands)	09/30/2020	09/30/2019		
	(Calousarius)	6 months	6 months	Change	
	Product sales, royalties	-	-	-	-
	Income from development services	1,226	625	601	96%
	Licenses, milestones	-	1,332	(1,332)	-100%
	Income from polymer sales	-	-	-	-
	Revenue	1,226	1,957	(731)	-37%
	Other income from ordinary activities	1,920	1,952	(32)	-2%
Α	Income from ordinary activities	3,146	3,909	(763)	-20%
	Cost of goods & services sold	-	-	-	0%
	Research and development expenses	(7,759)	(7,926)	167	-2%
	Sales & marketing expenses	(758)	(1,241)	483	-39%
	General and administrative expense	(2,760)	(2,778)	18	-1%
В	Total operating expenses	(11,277)	(11,945)	668	-6%
	Recurring operating income/(expense)	(8,131)	(8,036)	(95)	1%
	Other operating expenses/income	(20)	(56)	36	-64%
	Operating income/(expense)	(8,151)	(8,092)	(59)	1%
	Gross financial debt income/expense	(2,446)	(917)	(1,529)	167%
	Other financial income/costs	(157)	69	(226)	-328%
C	Financial income/(expense)	(2,603)	(848)	(1,755)	207%
	Income/(Loss) before tax	(10,754)	(8,941)	(1,813)	20%
	Tax income/expense	-	(57)	57	-
	Net income/(loss)	(10,754)	(8,999)	(1,755)	20%
	Attributable to owners of MedinCell	(10,754)	(8,999)		
	Attributable to non-controlling interests	-	-		
	EPS (Earnings per Share), €	(0.51)	(0.45)		
	Diluted EPS, €	(0.51)	(0.45)		

# Balance sheet summary

43 M€ of debt: The increase in non-current debt is due to the receipt between May and June of 11.9 M€ of stateguaranteed loans (PGE).

(€ thousands)	09/30/2020	03/31/2020
Total non-current assets	8,619	9,573
Total current assets	32,700	17,734
Total assets	41,319	27,307
Consolidated equity	(11,841)	(15,958)
Total non-current liabilities	44,675	36,663
Total current liabilities	8,485	6,602
Total liabilities and equity	41,319	27,307

#### **About MedinCell**

MedinCell is a clinical stage pharmaceutical company that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology with active ingredients already known and marketed. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, i.e. compliance with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. The BEPO® technology makes it possible to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. Based in Montpellier, MedinCell currently employs more than 130 people representing over 25 different nationalities.

#### **Contacts**

MedinCell
David Heuzé
Communication leader
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap Mathilde Bohin / Louis-Victor Delouvrier Investor relations medincell@newcap.eu +33 (0)1 44 71 98 53 NewCap Nicolas Merigeau Media relations medincell@newcap.eu +33 (0)1 44 71 94 98

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